REGULATORY GUIDE B8

COMPLYING WITH TITLE B - BONE DENSITOMETERS

South Carolina Department of Health
and Environmental Control

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REGULATORY GUIDE B8
COMPLYING WITH TITLE B – BONE DENSITOMETERS

Each facility that is registered with the Department is required to comply with Regulation 61-64, X-Rays (Title B), which are the regulations concerning x-ray equipment. This guide is intended to assist facilities using bone densitometry equipment in complying with Title B regulations.

Facility Registration Approval (see RHB 2.4)

Prior to installation the facility must submit the following information to the Department:

- Facility name, location address, and mailing address.
- The name of the Radiation Safety Officer (RSO), who is responsible for radiation protection, and the individual's qualifications to serve in this capacity.
- Type and make of x-ray equipment to be installed.
- Operating policies and procedures. See below under "Operating Procedures".
- A training plan, to include operator certification by the South Carolina Quality Standards Association and facility specific training. See below under "Training".
- A shielding plan or area survey, if required, as well as any application and shielding review fees.

After review and approval of this information and receipt of application and shielding review fees, the Department will issue a Facility Registration Approval.

A FACILITY SHALL NOT INSTALL OR CAUSE TO BE INSTALLED AN X-RAY PRODUCING MACHINE UNTIL THE DEPARTMENT HAS ISSUED A FACILITY REGISTRATION APPROVAL.

While it is the facility's responsibility to submit the information for facility registration approval, **vendors** are required to ensure that the approval has been granted before the equipment is installed. If the equipment is installed without facility registration approval, the vendor will be in violation of RHB 2.4.4 which states, AIt shall be unlawful for any person to install x-ray producing equipment until the facility acquiring that equipment has received a facility registration approval from the Department.≅

Registration (See RHB 4.10.1)

With the Facility Registration Approval Letter, the Department will also send registration forms to the facility, which must be completed and returned within thirty (30) days after acquisition of the unit. After the registration forms are completed and submitted, the equipment will be registered, and the facility will be sent an invoice for registration fees. Thereafter, an annual fee statement will be sent in January of each year. The registrant is also required to report, in writing, any changes that affect the x-ray facility or the x-ray equipment. This includes change of location or mailing address, acquiring or disposing of x-ray equipment, changes in operating procedures that may affect an approved shielding plan, and any changes in the approved training plan or operating procedures.

Shielding Requirements (see RHB 4.10.2)

1) Table units - A shielding plan or radiation area survey , which is acceptable only if prior approval is given, is required for table units. Shielding plans must be submitted and approved by this Department prior to installation, or the facility must indicate in writing that an area survey will be performed and submitted to this Department within 30 days of installation. Both shielding plans and radiation area surveys require the submission of a shielding review fee.

2) Peripheral units - A shielding plan or survey is not required for peripheral units. The bone densitometer must be located in a controlled area.

Administrative Requirements (see RHB 4.10.4)

The following items are required:

1) Radiation area signs. Each entrance into a radiation area must be posted with a radiation area sign.

2) A sign must be posted in a conspicuous area that notifies patients to inform the technologist if they are pregnant or might be pregnant.

3) A "Notice to Employees" sign (SC-RHA-20) must be posted in an area where it can be reviewed by all employees. You may contact the Department for a copy of this sign.

4) The x-ray control must have a label on it which states "WARNING: This x-ray unit may be dangerous to patient and operator unless safe exposure factors and operating instructions are observed."

5) A patient log is required at each facility. The patient log must show the patient's name, the type of examination, and the dates the examinations were performed. When the patient or film is held by a human, then the name of the human holder must be recorded.

6) Approval for Screening – Screening is defined as "testing using x-ray machines for the detection or evaluation of health indications when such tests are not specifically and individually ordered by a licensed practitioner of the healing arts legally authorized to prescribe such x-ray tests for the purpose of diagnosis or treatment." A screening program cannot be initiated without prior approval from the Department. The Department is not approving bone density screening programs at this time.

Operating Procedures (see RHB 4.2.4)

All facilities using x-ray bone densitometer units are required to establish an operating policy and procedure manual. The manual is required to contain the following:

1) **Policies and Procedures for Patient Holding.** The procedures must state whether or not, as a matter of policy, patients and/or films will be held at that facility. The availability and use of restraining devices must be addressed. The procedures must indicate the individual projections where mechanical holding devices cannot be used, and a human holder is required. The process to select a human holder must be documented, as well as the procedures that the human holder is to follow. Whenever possible, an adult accompanying the patient should be used for holding. Pregnant females should not be used to hold a

patient. Methods for protecting the human holder, such as wearing aprons and gloves, must be included. If a facility is required to routinely hold patients and/ or films, then procedures to ensure that no one person is used routinely to hold patients must be included. If an employee may be required to hold patients or films more than three times a quarter, then the procedures must also address personnel monitoring of human holders.

The lead aprons and gloves must be checked annually for cracks and holes that could compromise the radiation protection they provide. This testing must be documented. Records of this testing must be kept for two years or until the next Department inspection.

2) **Policies and Procedures for Pregnant Workers.** Procedures to be followed when a worker declares her pregnancy must be included, as well as methods of informing workers of the total exposure received during gestation. A facility may choose to change the work assignments of a pregnant worker, or they may not. Either is acceptable to the Department, as long as regulatory radiation limits are maintained. If a facility has policies to change the work assignments of pregnant workers, then those policies should be stated. Pregnant workers have a right to request a personnel monitoring device. The Nuclear Regulatory Commission's Regulatory Guide 8.13, "Instruction Concerning Prenatal Radiation Exposure" should be used for guidance concerning pregnant workers. This guide is available from the Superintendent of Documents, U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20013-7082.

3) **Policies and Procedures for Pregnant Patients.** The procedures must include methods for determining possible patient pregnancy, and whether or not pregnant patients will be x-rayed. Prescription of x-ray examinations of pregnant or possibly pregnant patients shall assure that medical consideration has been given to possible fetal exposure and appropriate measures are taken.

4) **Policies and Procedures for Personnel Monitoring.** Personnel monitoring devices, or film badges, are not required. However, if they will be used, then there must be a policy and procedure on the use of these devices. The procedures must tell employees how to correctly use personnel monitoring devices and how to care for personnel monitoring devices. The name of the person responsible for distribution, collection, and records of badges must be stated. The location of control badges must be given. The policies for reporting and investigating overexposures must be stated. A prohibition against intentionally exposing any control or personnel badge must be included. Procedures must also be included instructing workers on how they may obtain the results from the monitoring. The Department recommends instituting a personnel monitoring system for a period of at least one year to ensure that all individuals entering a restricted area do not receive a dose in excess of 10 percent of the allowable exposure limits. If procedures require an individual=s extremities to be in or near the primary beam, then ring badges should also be used.

5) **Methods for Quality Assurance.** The only requirement for this policy is that a statement be made to the effect that the manufacturer's recommended schedule for maintenance be followed, and that the unit will not be used if the self-calibration fails.

6) **Procedures for Training New Employees.** See below under "Training." The procedures must include a statement indicating that all operators will be certified by the South Carolina Radiation Quality Standards Association (SCRQSA). For more information contact the SCRQSA at (803)771-6141.

Training (see RHB 4.2.3)

Each medical facility is required by RHB 4.2.3 to ensure that all x-ray operators possess a current, valid certificate from the South Carolina Radiation Quality Standards Association (SCRQSA). Each operator's current certificate must be displayed in public view. Licensed practitioners (physicians, chiropractors, podiatrists, etc.) are exempt from the certification requirements.

An operator is defined as one who applies ionizing radiation to humans for diagnostic or therapeutic purposes. An operator also includes anyone who performs x-ray exam setups, patient positioning, technique selection, therapy treatment setups, setting of treatment parameters, verification of treatment accessories, or documents daily treatments for a patient's chart.

Each operator, including physicians, is also required to receive training specific to the equipment and procedures in use at the facility, including machine specific training, use of personnel monitoring devices, quality assurance procedures, and the operating procedures required by RHB 4.2.4. This training must be documented for each operator and maintained at the facility. For new employees, this training must begin within 30 days after employment.

The training records will be checked as part of the routine inspection by the Department. In addition, the department may request at any time to review the training records of an employee.

Prior Occupational Exposure (see RHB 3.20)

Each registrant has the responsibility to require an employee to disclose their previous occupational dose prior to working at the registrant's facility. The registrant must obtain a written, signed statement that states either that the worker had no prior occupational dose during the current calendar quarter or states the nature and amount of any prior occupational dose during the current calendar quarter. For the purpose of this statement, the current calendar quarter is interpreted to mean the most recently available calendar quarter. The registrant must maintain these written statements until the Department authorizes their disposition.

Occupational Exposure at Multiple Facilities (see RHB 3.4.4)

Each registrant is responsible for ensuring that an employee does not exceed yearly dose limits from all sources of radiation, not just sources located at the registrant's facility. The exposure that an employee receives at any facility must be recorded by each facility at which that employee works, if the employee is likely to receive more than 50% of the dose limit. The simplest way to achieve compliance with this requirement would be for an employee to be provided with a monitor to be worn at all facilities where employment occurs, and an individual monitor issued by each facility. Then, total occupational dose could be tracked, as well as doses received at individual facilities.

Inspections (see RHB 1.3)

The Department conducts routine periodic inspections of x-ray facilities on a priority system, based on the type of facility that is operating. The Department will also conduct inspections if a complaint is received, or if a facility requests an inspection. If violations are found on an inspection, a follow-up inspection may be conducted if the severity of the violations warrants it. Generally, the Department will send a Notice of Inspection letter to a facility about two weeks in advance of the inspection. Inspections by the Department are mandatory, but every attempt will be made to accommodate patient schedules. The Department does have the right to make unannounced inspections.

The inspection consists of checking the operation of the x-ray equipment, as well as checking administrative items

such as records. The facility can greatly assist the Department inspector by using the attached inspection checklist to ensure that all records are available for review. The checklist also contains some questions that will be asked by the inspector. Having this information readily available at the time of inspection will greatly facilitate the inspection process.

After a facility is inspected, the inspector will conduct an exit interview. The inspector will discuss any items of noncompliance, as well as any other items that the inspector deems relevant. The inspector will leave an inspection report at the conclusion of the inspection. The inspection report will cite any violations of the regulations. The inspector may also make recommendations concerning the x-ray equipment or the facility itself. A facility representative must sign the inspection report acknowledging receipt of the report. All violations are required to be corrected within 60 days of the inspection.

There may be some inspections which may require additional information before they are completed. In these situations, the inspector will send a written report to the facility within approximately two weeks of the inspection. After receiving the report, the facility has twenty days to respond, in writing, to the Department. This twenty day notification must indicate that corrective action will be taken to correct any violations that were found upon inspection. The Department will respond, in writing, to the twenty day notification, and will give a date by which all corrections must be made. The facility must notify the Department, in writing, by this date that corrective actions have been made.

The facility has the option of correcting recommendations. Each violations and recommendation must be addressed individually. Corrective action must be described for each violation and recommendation. It will not suffice to simply state that all violations and recommendations have been corrected. If a facility chooses not to accept a recommendation made by the Department, the facility should state that in their response. After the Department has received the sixty day notification and reviewed the corrective action, a Completed Corrective Action letter will be sent to the facility.

Misadministration (see RHB 1.11)

Misadministration means the administration of (1) radiation to the wrong patient (2) performance of a diagnostic procedure other than that ordered by a prescribing physician.

Each registrant must retain records of misadministrations. The record must contain the name of all individuals involved in the misadministration (including the physician, allied health personnel, the patient, and the patient's referring physician), the patient's social security number or identification number, a brief description of the event, the effect on the patient, and the action taken, if any, to prevent recurrence. The records of misadministration must be maintained for three years for diagnostic misadministrations.

The action that a registrant must take in response to a misadministration depends on the type of misadministration that occurs. When a misadministration involves a diagnostic procedure, the registrant shall promptly investigate its cause, make a record for Department review, and maintain the records for three years.

Overexposures (see RHB 3.25)

The registrant is required to report to the Department any exposure of an individual in excess of any limit in the regulations. The time frame for reporting overexposures depends on the exposure that an individual receives.

Immediate, 24 hour, and/or thirty day written notification may be required. See RHB 3.25 concerning radiation levels and the requirements for reporting.

Records (see RHB 1.10)

The registrant is required to maintain all records required to comply with or show compliance with Title B. These records include:

≅ Records showing receipt, transfer, use, storage, and disposal of all sources of radiation. (RHB 1.10.1)

≅ Records showing model and serial numbers of all controls and tubes. (RHB 1.10.2.1)

≅ Records of surveys, calibrations, maintenance, and modifications performed on the x-ray system and components, with the names of persons who performed such services. (RHB 1.10.2.4)

≅ Copies of all correspondence with the Department. (RHB 1.10.2.5)

≅ Records of misadministrations. (RHB 1.11)

≅ Records of prior occupational dose for employees. (RHB 3.20)

≅ Records of personnel monitoring results. (RHB 3.22.1)

≅ Records of employee training. (RHB 4.2.3)

≅ X-ray logs. (RHB 4.2.17)

≅ A scale drawing of the x-ray room showing occupancies of surrounding areas, and composition of all walls, or results of an area survey performed by a Class IX vendor showing radiation levels around the room, if applicable. (RHB 4.4.3)

≅ Any other records of routine checks or testing that are required to be carried out.

QUESTIONS

If you have questions, please feel free to call or write:

S.C. DHEC

Bureau Radiological Health
2600 Bull Street
Columbia, SC 29201
(803) 545-4400
FAX (803) 545-4412

REGULATORY GUIDES

B1 - Registration of X-ray Facilities and Equipment
B2 - Complying with Title B - Medical Facilities
B3 - Complying with Title B - Dental Facilities
B4 - Complying with Title B – Facilities Utilizing Analytical or Industrial X-Ray Equipment
B5 - Vendor Registration and Responsibilities
B6 - Shielding Plans
B7 - Complying with Title B - Mammography Facilities
B8 - Complying with Title B - Bone Densitometers
B9 – Complying with Title B – Veterinary Facilities

Visit our web site at: www.scdhec.net

CHECKLIST FOR DHEC INSPECTION (BONE DENSITOMETER)

Please have available the following records for the DHEC inspector:

___ Personnel monitoring reports.

___ Records of previous occupational dose for employees and records of dose for employees who work at other facilities.

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___ Patient logs.

___ Documentation of operator training. (SCRQSA certificates and facility specific training.)

___ Misadministration records.

___ A list of all operators of the x-ray equipment. This includes routine operators, as well as back-up operators and part-time operators. Indicate on the list the title of each operator, such as RT, RN, etc., and SCRQSA certificate number.

___ Operating procedures. (Including a written policy on Pregnant Workers, Pregnant Patients, Patient Holding, Personnel Monitoring, Training Procedures, and Quality Assurance.)

Please be familiar with, and be prepared to show the DHEC inspector the following items:

___ Posted radiation area signs.

___ Posted pregnancy posters.

___ Posted ANotice to Employees.≅